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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
HENLEY III,R	#3
ART UNIT	**PAPER NUMBER**
1205	

DATE MAILED: 02/19/93

02/19/93

WHITE & CASE
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 12/17/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire — 3 — month(s), ——— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-7 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

Claims 1-7 are presented for examination.

The papers submitted under 35 USC 119 on December 17, 1992 have been received and entered into the application.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 4 is rejected under 35 U.S.C. § 101 because the invention as claimed is directed to non-statutory subject matter. See Clinical Products v. Brenner, 149 USPQ 475 at 478 regarding the impropriety of claims reciting the "use" of an ingredient. Accordingly, this claim has not been further treated on the merits.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In further explanation:

(1) The parenthetical phrases appearing in claims 1-3 and 5-7 render these claims indefinite because it is unclear whether such phrases, in fact, are limitations. In order to overcome this point of rejection, applicants may wish to consider placing these phrases is non-parenthetical form.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Brattsand et al. and Murakami et al. in view of applicants acknowledgements at page 3 of the specification.

Brattsand et al. highlight a class of steroids of which budesonide is a member which possess anti-inflammatory activity and may be used to treat respiratory disorders including asthma. See the abstract and column 10, lines 7-8. The patentees also describe and exemplify various compositions at column 9, lines 1-7 and column 13 including pressurized and powdered aerosols for inhalation. (examples 9 and 10).

Murakami et al. highlight a class of beta-2 agonist alpha-aminomethylbenzyl alcohols of which formoterol is a member, i.e. 3-formylamino-4-hydroxy-alpha-[N-(1-methyl-2-p-methoxyphenylethyl) -aminomethyl]benzyl alcohol, Example 22, which are effective for relaxing bronchial smooth muscle in such conditions as asthma (column 7, lines 35-47. Pharmaceutical compositions including aerosol inhalations are highlighted at the paragraph bridging columns 7 and 8.

The differences between the above and applicants' claimed subject matter lie in that the references fail to highlight the combined use of budesonide and formoteral for treating a respiratory condition such as asthma where the ingredients are administered in sequence or together in one composition.

However, to the skilled artisan motivated by a reasonable expectation of success, it would have been obvious to reconcile these differences because of the common utility shared by the actives, namely of treating asthma.

It is considered prima facie obvious to combine two or more ingredients which are each taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used separately in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (C.C.P.A. 1980) and the cases cited therein.

Moreover, as acknowledged by applicant at page 3 of the specification, the artisan was well aware of treatments in which steroids and B_2-agonists are combined (i.e. EP 416950 and 416951).

The determination of the optimum therapeutic regimen to employ would have been a matter well within the purview of the skilled medical artisan given his/her level of ordinary skill.

For these reasons, the claims are deemed to be properly rejected under 35 USC 103 and none are allowed.

In order to ensure a quality examination of the instant application, applicants should provide the Examiner with copies of the references listed and discussed at page 3, lines 21, 22 and 25-32 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Henley whose telephone number is (703) 308-4652.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Henley: ach
February 12, 1993
February 17, 1993

Raymond J. Henley III

RAYMOND J. HENLEY III
PATENT EXAMINER
GROUP 120 - ART UNIT 125